

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2031806	(X3) Date Survey Completed 03/08/2018
Name of Provider or Supplier Johnson Memorial Hospital	Street Address, City, State 142 Hazard Avenue, Enfield, CT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a policy in place to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's competency records on 3/8/18 revealed the following: a. The laboratory did not have a policy in place to assess the competency of the general supervisor (GS). b. Competency documentation for hematology had the name and address of a different site where the GS also worked. c. Competency documentation for the GS hired within the last 2 years was not available for this site. 2. Staff interview with the GS on 3/8/18 at 11:10 AM confirmed the above findings.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to document routine maintenance and function checks for laboratory equipment in the specialty of hematology. Findings include: 1. Record review of the laboratory's microscope maintenance and PM documentation on 3/8/18 revealed documentation for the 2016</p>

microscope PM was not available. 2. Staff interview with general supervisor (GS) on 3/8/18 at 11:00 AM confirmed the above findings. 3. The laboratory performs 444 manual white blood cell differentials annually in the specialty of hematology.

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to document function checks to ensure proper functioning prior to patient testing. Findings include: 1. Record review on 3/8/18 of the laboratory's 2017 maintenance and function check records for the centrifuge used to spin patient samples for send out tests revealed the following: a) Documentation was only available for electrical checks. b) Documentation was not available for the timer and RPM calibration. 2. Staff interview with the general supervisor (GS) on 3/8/18 at 10:20 AM confirmed the above findings.